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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,732	12/20/2001	Thomas J. Bormann	440525/PALL	9021
23548	7590	01/16/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,732

Applicant(s)

BORMANN ET AL.

Examiner

Krishnan S Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-22 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-22 and 31-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 1-13, 15-22 and 24-34 are pending.

Election/Restrictions

Applicant's election with traverse of claims 1-13, 15-22 and 31-34 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there is no demonstration that the search and examination of all pending claims would entail a serious burden on the examiner, as required by section 803 of the MPEP, even though the claimed inventions in the two groups could be independent and distinct. This is not found persuasive because the restriction is based on PCT Rule 13.1 and 13.2, because the application is filed under 35 USC 371. It may be noted that the restriction is proper even if this was a US case because the two groups fall under different classification, and therefore, require different search (MPEP 808.02). Group I would fall in class 210/435 and group II would fall in 210/645:

The requirement is still deemed proper and is therefore made FINAL.

Examiner apologizes for the misunderstanding re the election as being without traverse.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 15-22 and 31-34, rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0630 675 A1 in view of Onishi et al (US 5,547,576)

EP-675 teaches a filter comprising one or more elements having surface nitrogen and oxygen (see page 5 lines 1-18), elements surface-hydroxylated relative to the bulk as in claims 1-9 and 31-34 (see also page 4 lines 20-27: PVA and polyurethanes have surface hydroxyl groups; page 6 lines 23-25; page 7 lines 27-56). Multiple layers are taught as in claims 5 and 6 (page 4 lines 12-16 and 49-56, col 7 lines 27-56); additional layers are only duplication ((Note: mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*; *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), and a mere reversal of parts (*In re Gazda* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) or rearrangement of parts (*In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) are unpatentable). Element hydroxylated is also aminated as in claim 7 and 8 (page 5 lines 1-33). The hydroxylated surfaces include carboxyl groups as in claim 10 (page 5 lines 3-18). EP 675 teaches separate elements, one set having N/O ratio and another set having excess surface hydroxyl groups as in the instant claims, and separate elements having excess surface carboxyl and excess surface hydroxyl groups as in claim 32 and 33 (col 5 lines 1-18). EP 675 teaches filter for filtering and separating leukocytes and platelets having elements (layers) with excess surface N/O

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and carboxy groups (page 5 lines 9-18), and other elements having excess surface hydroxy groups (page 7 lines 27-56).

EP does not specifically teach a filter element with substantially non-hydroxylated surface. However, EP teaches graft copolymerization of cationic compounds like amines by plasma treatment as disclosed by the applicant (incorporated ref: US 5,258,127) to make filter having surface nitrogen and oxygen. The compounds used for surface treatment, amines and glycidyl methacrylate, do not have hydroxyl groups. Onishi teaches a filter with substantially non-hydroxylated surface having nitrogen and oxygen in the instant claims for removal of leucocytes and platelets from blood products (Table I, example 6: compounds used do not have hydroxyl groups, and hydroxyl groups are not formed in the reactions). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Onishi in the teaching of EP 675 for a filter to filter and separate leukocytes and platelets from plasma, as taught by EP 675. One would use the teaching of Onishi to modify the teachings of EP 675 because Onishi filter gives better separation of platelets (compare sample 1 of Table I of Onishi with Table 2 of EP 675). Re the ratio of N/O, Onishi teaches equivalents of amino groups, but EP'675 in view of Onishi does not specify the N/O ratio. However, N/O ratio can be optimized for the hydrophilicity/surface cationic charge required for the separation. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).

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Re claims 11-13 and 15, zeta potential as in claim 11, and CWST as in claims 12, 13 and 15 are all material properties, and would be similar for similar materials. [[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977))).

Claims 16-22 add further elements as follows: EP teaches a housing with inlet and outlet as in claim 16 (abstract), plasma passes through and leukocytes and platelets do not as in claim 17 (see tables); re C3a as in claims 18, 19 and 22, similar filter structure would give similar results for C3a as obtained by the applicant. Re leukocyte and platelet counts in the plasma product, this factor would depend on the counts in the original plasma in addition to the efficiency of the filter (see table 1 of Onishi and table 2 of EP 675).

Response to Arguments

Applicant's arguments with respect to instant claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Krishnan Menon
Patent Examiner


W. L. WALKER
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